CTMS Adverse Events Reporting SIG Teleconference
Meeting Minutes

Meeting Date	Wednesday, August 11, 2004 3:30 – 4:30 PM EDT
Attendees:	**Working group coordinator**: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton) **Participants:**

Name	Email	Organization
Amy Cox	acox@coh.org	City of Hope
Brenda Duggan	dugganb@mail.nih.gov	NCICB
Andrea Hwang	ychwang@uci.edu	University of California - Irvine
Erin Iturriaga	iturriae@mail.nih.gov	DCP
Bob Lanese	robert.m.lanese@case.edu	Case Western
Valerie Monaco	monacov@upmc.edu	University of Pittsburgh
Joyce Niland	jniland@coh.org	City of Hope
Susan Pannoni	spannoni@coh.org	City of Hope
Diane Paul	funnylady93@earthlink.net	CARRA
Bill Schaller	schaller.william@mayo.edu	Mayo Clinic
Hemant Shah	hshah@coh.org	City of Hope
John Speakman	speakman@biost.mskcc.org	Memorial Sloan Kettering

Agenda

I. Review of Minutes:
- July 16, 2004 Teleconference
- July 19 – 20, 2004 Quarterly In-Person Meeting

II. Update from the Face-to-Face Meeting

III. Proposed AE System High Level Diagram Review

IV. Update on MedWatch Ballot with HL7: Dr. Hemant Shah

V. Next Quarterly In-Person Meeting at City of Hope

	a October 18 – 19, 2004 b November 15 – 16, 2004 c November 16 – 17, 2004 VI. Future Plans VII. Next Meeting: September 3, 2004 3:00pm – 4:00pm EDT 12:00pm – 1:00pm PDT
General discussion points raised by participants:	• Flow diagrams for identifying and reporting adverse events was described from the perspective of cancer centers, the caBIG adverse events system and the patient. A suggestion to add a node for patient self-reporting of adverse events where both the system and the patient receive confirmation of receipt/delivery was made. • Change of terminology from "review bodies" to IRBs on page 2 of the identifying and reporting adverse events flow diagram was suggested to avoid confusion. • The process for reporting of significant toxicities (for example, level 5) and aggregating severe adverse events (SAE) was discussed. • Hemant Shah presented an overview of individual case safety report ballot. The presentation covered the messaging aspects related to adverse events reporting to meet the requirements of FDA.
Action items:	• Get electronic changes to Activity Diagram from CTEP and complete the CTEP workflow • Obtain rule tables from CTEP for triggering AE reporting • Flowchart of DCP AE information flow • Complete domain specific vocabulary analysis, incorporating 70 attributes from Medwatch HL7 ballot • Draft optimal idealized workflow for harmonized unified AE reporting module